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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,673	03/23/2005	Tatsuo Hoshino	K21409USWO C038435/018565	2412

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1652	

MAIL DATE	DELIVERY MODE
05/11/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,673	HOSHINO ET AL.	
	Examiner	Art Unit	
	GANAPATHIRAMA RAGHU	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *3,4,9-12,14,15,17 and 18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 6-8, 13 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Application Status

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/09/09 has been entered.

In response to the Final Office Action dated 02/01/2008 and an Advisory dated 08/27/2008, applicants' filed an RCE received on 03/09/09. Applicants' have presented the same set of claims and the same arguments that were filed after Final 02/01/2008 and before filing of the Appeal-brief.

Withdrawn-Claim Rejections: 35 USC § 112, second paragraph

Previous rejection of claims 1, 2, 6, 7 and 13 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is being withdrawn in view of the amendments to the claims.

Withdrawn-Claim Rejections 35 USC § 102

Previous rejection of claims 2, 8, 13 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Sugisawa et al., (1995) is being withdrawn in view of the amendments to the claims and persuasive arguments by the applicants.

New-Claim Objections

Claims 1 and 2 recite the phrase "...the complementary sequence thereof", it is not clear to the examiner whether the complementary polynucleotide claimed is full

length or partial complement of the claimed sequence, examiner suggests amending the claims to recite "the full-length complementary sequence thereof".

New-Claim Rejections 35 USC § 112-Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 and 2 and claims 6, 7 and 13 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1, line 6 and Claim 2, line 19 recites "under suitable culturing conditions…", since the claim does not set forth any steps involved in the method i.e., either a host cell or a transformed host cell expressing the polypeptide of SEQ ID NO: 2, it is unclear what method applicant is intending to encompass. A claim is indefinite where it merely recites a method without any active, positive steps delimiting how this method is actually practiced.

Claim 1 and 2 and claims 6, 7 and 13 depending therefrom are rejected under 35 U.S.C. 101 because the claimed recitation of "a suitable culturing conditions, without setting forth any steps involved in the process i.e., host cell or transformed host cell, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim 8 and claim 16 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 8, line 4 recites the phrase "derivable from *G. oxydans* DSM 4025. It is not clear to the examiner as to what the phrase "...derivable from..." means in the context of the above claim, is this synonymous with "obtained from specific strain or source" or does it include natural and man-made mutants thereof from any source. Furthermore, literally while the term "derived" means to "to isolate from or obtain from a source", the above term could also mean "to arrive by reasoning i. e., to deduce or infer" or also mean "to produce from another substance". It is noted that while the term "derivable" will encompass proteins naturally found in any microorganism or cells, the term in its broadest reasonable interpretation will also encompass any variant artificially created enzyme from any microorganism or cell, wherein said enzyme has the recited physico-chemical properties. Since a protein activity is defined by its structure, if a man-made variant of said enzyme has similar structure (i. e., amino acid sequence) and physico-chemical properties as that of a protein isolated from any source which is not a *G. oxydans* DSM 4025, the term "derivable..." would not allow one of skill in the art to differentiate between these proteins, especially the claim language has no structure associated with the physico-chemical property and said enzyme activity. Therefore, unless applicant has defined the term "derivable..." as equivalent to "obtained from the specific source with specific structure", the term "derivable..." does not further limit the recited enzyme. Clarification and correction is required.

Maintained-New Matter-Claim Rejections 35 USC § 112

Claims 1, 2, 8 and claims 6, 7, 13 and 16 depending therefrom are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1, 2, 8 are rejected because the phrase "directly" is new matter. The scope of the process for the production of L-ascorbic acid comprising: (a) contacting an enzyme with a substrate which is selected from the group consisting of L-gulose, L-galactose, L-iodose and L-talose; (b) converting the substrate "directly" into L-ascorbic acid .... as claimed was not contemplated in the specification as originally filed. The process for the production of L-ascorbic acid comprising: (a) contacting an enzyme with a substrate which is selected from the group consisting of L-gulose, L-galactose, L-iodose and L-talose; (b) converting the substrate into L-ascorbic acid .... as in original claims 1, 2, 8 has a different scope than the process now claimed.

Applicants have traversed this rejection with the arguments that:

1) applicants' claim to have support for this amendment in the specification at for example, page 1, lines 1-2; page 2, lines 8-12; page 2, line 25 to page 3, line 9 and lines 27-29; in examples 1-4 and Tables 1-4 and in original claims 1 and 5 (pages 13-16 of applicants response dated 03/09/09).

Reply 1): In the sections pointed out by the applicant for the support, examiner is unable to find either explicit or implicit meaning wherein the claims or the specification construes/contemplates converting the substrates directly into L-ascorbic acid by

catalytic activity of a polypeptide having the amino acid sequence of SEQ ID NO: 2. Examiner has thoroughly explained his position in the previous Office Action (05/11/2007) regarding interpretation of claims and support in the specification and therefore continues to hold the position that: 1) The claims as written "A process for production of L-ascorbic acid comprising: is interpreted as "open language" and therefore the process for production of L-ascorbic acid can comprise other elements in the reaction. 2) Furthermore, neither the claims as written nor the specification explicitly states that the said process for the production of L-ascorbic acid is a direct one step-conversion of claimed substrates into L-ascorbic acid as amended. The said process of production of L-ascorbic acid was carried out under specific cellular context *in vivo*, i.e., production of L-ascorbic acid in a process comprising: contacting an enzyme having the amino acid sequence of SEQ ID NO: 2 encoded by a polynucleotide of SEQ ID NO: 1, said polypeptide expressed in a specific strain of *E.coli* JM 109 having the activity to produce L-ascorbic acid from substrates L-gulono-1,4-lactone/L-gulonic acid from L-gulose and from L-galactono-1,4-lactone/L-galctonic acid or conversion of substrate L-galactose to L-galactono-1,4-lactone/L-galactonic acid and L-ascorbic acid under suitable culture conditions (as in Examples: 1-4 and Tables 1-4, pages 8-10; and culture conditions: lines 15-28, page 6 of specification) and therefore said bacteria may provide other necessary enzymes either for the production of intermediate products of L-ascorbic with claimed substrates or for the final conversion of the intermediate products to L-ascorbic acid. Therefore said process of production of L-ascorbic acid does not involve converting substrates directly into L-ascorbic acid.

Furthermore claimed recitation of a use of Enzyme B … (in page 1, lines 1-2 of specification), without setting forth any steps involved in the process, results in an improper definition of a process (See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). The recitation of phrase "use" without any active, positive steps delimiting how this use is actually practiced, renders the term indefinite and failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

2) Applicants argue, "Furthermore, the international Preliminary Examination Report of the instant application clearly recognizes such direct one step process....See e.g., Form PCT/Separate Sheet/409, item V, section 2.1" (page 16 of applicants response dated 03/09/09).

Reply 2): Applicants have cited selected sections of said report, The cited Form PCT/Separate Sheet/409, section 3, pages 7-8 of said report clearly observed the following regarding the instant invention, examiner is reproducing page 8 from said report below and has underlined the relevant observations of said International Report that the instant process involves production L-ascorbic acid in *E.coli* JM109 transformed with the gene encoding an enzyme having the amino acid sequence of SEQ ID NO: 2…

Document D1 discloses that an isolated enzyme having the amino acid sequence of SEQ **ID** NO: 2 uses L-idose as substrate to produce L-idonic acid but not L-ascorbic acid. Document D4 discloses that E. coli JM109, the organism used in examples 1 - 4 of the present application, itself is capable of producing 2-keto-L-gulonate (page 455, right-hand column, paragraph 4; table 1).

The present application discloses only the production of L-ascorbic acid in E. coli JM109 transformed with a gene encoding for an enzyme having the amino acid sequence of SEQ ID NO: 2. It appears that the process for L-ascorbic acid production described in the present application depends on the presence of E. coli JM109 or

other additives. Therefore, the present application does not disclose how to produce L-ascorbic acid by using only the isolated enzyme having the amino acid sequence of SEQ ID NO: 2. It seems that additional technical features, e.g. the use of E. coli JM109, besides an enzyme having the amino acid sequence of SEQ ID NO: 2 are necessary to arrive at the claimed products.

Since independent claims 1 - 4, and 8 - 10 do not contain these features, they do not meet the requirement following from Article 6 PCT taken in combination with Rule 6.3 (b) (I), (ii) PCT that any independent claim must contain all the technical features essential to the definition of the invention.

Furthermore, the subject-matter of claims 1 - 4, and 8 - 10 is insufficiently disclosed (Article 5 PCT).

3.3
Examples 1 and 3 of the present application describe the production of L-ascorbic acid from L-gulose and L-galactose when given as substrate to E. coli JM109 transformed with said enzyme. However, the present application shows no evidence that the experimental setup described for the production of L-ascorbic acid from L-gulose and L-galactose is also feasible for the production of L-ascorbic acid from the other substrates mentioned in claims 1,2, and 8, especially since this might involve multiple steps. Therefore, the application does not meet the requirement of Article 5 PCT, since the invention is not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art over the whole scope claimed.

Hence, applicants' arguments have been considered and they are found to be un-persuasive and therefore the rejection is sustained.

Maintained-Claim Rejections: 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 6-8, 13 and 16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the production of L-ascorbic acid comprising: contacting an enzyme having the amino acid sequence of SEQ ID NO: 2 encoded by a polynucleotide of SEQ ID NO: 1, said polypeptide expressed in a specific strain of *E.coli* JM 109 having the activity to produce L-ascorbic acid from substrates L-gulono-1,4-lactone/L-gulonic acid from L-gulose and from L-galactono-1,4-lactone/L-galctonic acid or conversion of substrate L-galactose to L-galactono-1,4-lactone/L-

galactonic acid and L-ascorbic acid under suitable culture conditions (as in Examples: 1-4, pages 8-10; and culture conditions: lines 15-28, page 6 of specification). However, the specification does not reasonably provide enablement for a process for the production of L-ascorbic acid comprising: contacting an enzyme with a substrate selected from the group consisting of L-gulose, L-galactose, L-idose, L-talose, L-gulono-1,4-lactone, L-gulonic acid, L-galactono-1,4-lactone, L-galactonic acid, L-idono-1,4-lactone, L-idonic acid, L-talono-1,4-lactone and L-talonic acid and converting the substrate directly into L-ascorbic acid by catalytic activity of the polypeptide comprising the amino acid sequence of SEQ ID NO: 2, encoded by the polynucleotide of SEQ ID NO: 1 under undefined stringent hybridization and wash conditions and under specific defined process conditions such as pH, temperature and time in which said substrates are allowed to react with said enzyme. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with the claims.

Applicants have traversed this rejection with the arguments that:

"Initially, we note that with a view towards furthering prosecution, claims 1 and 2 have been amended to delete recitations of an amino acid sequence with 90% sequence identity and with activity to produce L-ascorbic acid. Thus, the examiner rejection with respect to such an amino acid sequence are rendered moot…Additionally, we note that claims 1-2 have been amended to recite specific hybridization conditions…" (page 16 of applicants' response dated 03/09/09).

Reply: Examiner as withdrawn rejections directed towards "hybridization conditions" and "90% sequence identity".

However, as argued above, examiner continues to hold that "The said process of production of L-ascorbic acid was carried out under specific cellular context ***in vivo***, i.e., production of L-ascorbic acid in a process comprising: contacting an enzyme having the amino acid sequence of SEQ ID NO: 2 encoded by a polynucleotide of SEQ ID NO: 1, said polypeptide expressed in a specific strain of *E.coli* JM 109 having the activity to produce L-ascorbic acid from substrates L-gulono-1,4-lactone/L-gulonic acid from L-gulose and from L-galactono-1,4-lactone/L-galctonic acid or conversion of substrate L-galactose to L-galactono-1,4-lactone/L-galactonic acid and L-ascorbic acid under suitable culture conditions (as in Examples: 1-4 and Tables 1-4, pages 8-10; and culture conditions: lines 15-28, page 6 of specification) and therefore said bacteria may provide other necessary enzymes either for the production of intermediate products of L-ascorbic with claimed substrates or for the final conversion of the intermediate products to L-ascorbic acid. Therefore said process of production of L-ascorbic acid does not involve converting substrates directly into L-ascorbic acid and examiner is unable to find any support for claims as written. Examiner's position is also supported by the International Search Report: page 8 from said report is reproduced below and examiner has underlined the relevant observations of said International Report, said report clearly and unequivocally supports examiner's position in that the instant process involves production L-ascorbic acid in *E.coli* JM109 transformed with the gene encoding an enzyme having the amino acid sequence of SEQ ID NO: 2.

Document D1 discloses that an isolated enzyme having the amino acid sequence of SEQ **ID** NO: 2 uses L-idose as substrate to produce L-idonic acid but not L-ascorbic acid. Document D4 discloses that E. coli JM109, the organism used in examples 1 - 4 of the present application, itself is capable of producing 2-keto-L-gulonate (page 455, right-hand column, paragraph 4; table 1).

The present application discloses only the production of L-ascorbic acid in E. coli JM109 transformed with a gene encoding for an enzyme having the amino acid sequence of SEQ ID NO: 2. It appears that the process for L-ascorbic acid production described in the present application depends on the presence of E. coli JM109 or other additives. Therefore, the present application does not disclose how to produce L-ascorbic acid by using only the isolated enzyme having the amino acid sequence of SEQ ID NO: 2. It seems that additional technical features, e.g. the use of E. coli JM109, besides an enzyme having the amino acid sequence of SEQ ID NO: 2 are necessary to arrive at the claimed products.

Since independent claims 1 - 4, and 8 - 10 do not contain these features, they do not meet the requirement following from Article 6 PCT taken in combination with Rule 6.3 (b) (I), (ii) PCT that any independent claim must contain all the technical features essential to the definition of the invention.

Furthermore, the subject-matter of claims 1 - 4, and 8 - 10 is insufficiently disclosed (Article 5 PCT).

3.3
Examples 1 and 3 of the present application describe the production of L-ascorbic acid from L-gulose and L-galactose when given as substrate to E. coli JM109 transformed with said enzyme. However, the present application shows no evidence that the experimental setup described for the production of L-ascorbic acid from L-gulose and L-galactose is also feasible for the production of L-ascorbic acid from the other substrates mentioned in claims 1,2, and 8, especially since this might involve multiple steps. Therefore, the application does not meet the requirement of Article 5 PCT, since the invention is not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art over the whole scope claimed.

New-Claim Rejections: 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 8 and claim 16 depending therefrom are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 8 recites "… *G. oxydans* DSM 4025".

It is apparent that a strain of *G. oxydans* DSM 4025 is required to practice the claimed invention. As such the biological material must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the requirements of 35 USC112, first paragraph, may be satisfied by a deposit of a strain of *G. oxydans* DSM 4025. The specification does not disclose a repeatable method to obtain a strain of *G. oxydans* DSM 4025. It is noted that there is no indication in the specification as to the public availability. If a deposit was made under the terms of Budapest Treaty, then a statement, affidavit or declaration by Applicants, or a statement by an attorney of record over his/her signature and registration number, or someone empowered to make such a statement, stating that the invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. In order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, applicant may provide assurance of compliance by statement, affidavit or declaration, or by someone empowered to make same, or by a statement by an attorney of record over his /her signature and registration number showing that:

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting the patent;

(c) the deposit will be maintained in public depository for a period of 30 years, or 5 years

after the last request or for the enforceable life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and the deposit will be replaced if it should ever become inviable.

Summary of Pending Issues

The following is a summary of issues pending in the instant application.

1. Claim 1, 2 and 8 and claims 6, 7,13 and 16 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

2. Claims 1, 2 and 8 and claims 6, 7,13 and 16 depending therefrom are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for New-matter and scope of enablement.

Allowable Subject Matter/Conclusion

None of the claims are allowable.

Final Comments

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathirama Raghu whose telephone number is 571-272-4533. The examiner can normally be reached between 8 am-4: 30 pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Nashaat Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of the application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Ganapathirama Raghu/
Patent Examiner
Art Unit 1652